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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/280,279	03/29/1999	JON M. MILLER	MILLER.P001	5533

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/280,279	MILLER, JON M.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on December 22, 2003 has been entered. Any issue that is not addressed in this Office Action is considered obviated in view of Applicant's arguments. The effective filing date for this Application is March 29, 1999.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 29-32, 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Deutsch et al (CNS Drugs, 1997, 8(4): 276-284).

Examiner raised this issue during an interview in November of 2003. in response to Applicant's arguments to this rejection, Examiner states that a recitation of the intended use of the claims drawn to a process does not impart patentability, unless the intended result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

2. Here, the rejected claims require two process steps: (a) administering psychotropic active compound to a patient and (b) administering a safe and effective amount of histamine H2-receptor antagonists to same patient. Deutsch discloses the same process steps regardless of the intended use. There is no manipulative difference between the process steps of the instant claims and those taught by Deutsch. Therefore, Deutsch's method inherently anticipates the limitations of the instant claims.

Examiner suggests incorporation of a limitation to narrow the scope of the patients. Such limitations as "patients in need of such therapy" or "patient in need of minimizing weight gain weight" could potentially overcome the inherency rejection.

3. Claims 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg US patent 5,897,910 in view of Deutsch et al (CNS Drugs, 1997, 8(4): 276-284).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that there is no recognition in Rosenberg for the intended use of the instantly claimed method or compositions. (see Response at page 23). Applicant particularly points out that nothing in the references teaches anything about methods for preventing weight gain or even the combination of these particular drugs for any method. (see *Id.*).

4. First, Examiner responds that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the analysis must consider what would have been suggested to those of ordinary skills in the art when they take the teachings of references collectively; not whether there is an express suggestion for a specific limitation in any or all of the cited references. Examiner believes that the combined teachings of the references renders the claims obvious.

Rosenberg teaches process of making covered tablets wherein the tables comprising "a mixture of one or more pharmaceutically active ingredients." (see claim 1, col 7, lines 29-31). Therefore, there is general knowledge to combine any of combination of drugs suitable for a therapeutic purpose. Such combination can include clozapine or haloperidol (col 6, lines 15-17), mood stabilizing agents such as valporic acid (col 6, line 47) and histamine H2 antagonists such as cimetidine, famotidine, or nizatidine (col 6, lines 1, 13, 32, 40).

Deutsch provides for at least one therapeutic purpose for a combination of an antipsychotic and histamine H2 antagonists. (abstract, pages 282). Thus, there is ample suggestion to one of ordinary skill in the art to combine an antipsychotic and a histamine antagonist for at least the purposes taught in Deutsch.

5. Second, Examiner takes opposite view to Applicant's arguments that neither of references teaches "even the combination of these particular drugs for any method." *Id.* In response, Examiner states that at least Deutsch teaches the combination of famotidine as an adjunctive treatment with molidone, an antipsychotic (see page 277, 279). Thus, there is a teaching in the cited art about the use of H2-antagonists and antipsychoitc in combination.

6. Also, please note that claims 29-31, 33-37, do not require any specific combination of drugs. They are merely directed to a combination of an antipsychotic and a histamine 2 antagonist. Thus, Applicant's arguments with respect to said claims are not commensurate with the scope.

7. Additionally, in response to applicant's argument that there is no suggestion to combine the references, as there is no specific reference to the use of instant drugs for preventing weight gain, the Examiner states that it is settled that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge generally available to one of ordinary skill in the art. Applicant appears to be ignoring the general knowledge available to one of ordinary skill in the art about the use of H2-antagonists for weight loss.

To establish the general knowledge available to one of ordinary skill in the art, Examiner points out that extra references or evidences may be used to establish a general knowledge in the art when a "[g]ap in a reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) See MPEP § 2124.

Accordingly, in support of the reasoning above, the knowledge generally available to one of ordinary skill clearly would include; for example, WO 92/00736 Patent ("WO '736") which was published in 23 January to Birketvedt et al. which

teaches that cimatiadine and other H2-antagonists can be used for weight loss (abstract, page 1, lines 10-15; page 6, lines 1-20). As WO '736 was published at least 8 years before the instant application was filed, the art of using H2-antagonists for weight loss was well available to one of ordinary skill in the art. Therefore, contrary to Appliant's position, there is ample motivation to combine the cited references at least for the purposes taught by Deutsch or based on the knowledge generally available in the art to utilize known clinical benefits of H2-antagonists

8. With respect to the Applicant's argument that the rejection of record merely amounts to an "obvious to try" analysis, Examiner draws Applicant's attention to the reasoning set forth *in In re O'Farrell*, 7 USPQ2d 1673, (CA FC1988).

The court *In re O'Farrell* reasoned that

> [T]he admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical;... In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. no direction as to which of many possible choices is likely to be successful. *In re O'Farrell*, 7 USPQ2d 1673, 1681, 1682 (CA FC1988).

Neither of these situations applies here. Examiner points out that Obviousness does not require absolute predictability of success. For obviousness under §103, all that is required is a reasonable expectation of success. *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); In re Clinton , 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976).

In this case, Deutsch teaches that when antipsychotic and a histamine 2 antagonist are combined, they provide a reasonable expectation of success for the therapeutic purpose described. Therefore, the combined references render the pending claims *prima facia* obvious, not "obvious to try."

9. Applicant has also argued that the ruling of *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985) is not applicable because the applicant is not attempting to claim the combination these drugs for all use. (see Response at page 25). In response, Examiner partially repeats the arguments presented above that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, and *In re Otto*, *supra*.

Thus, since intended does offer a patentable weight to product claims as reasoned above, Applicant is in a way claiming the combination of these drugs for all use. With respect to the process claims, no manipulative difference has been distinguished.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RUSSELL TRAVERS
PRIMARY EXAMINER